

REMARKS

Election of Species Requirement

Applicant was required to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The species are as follows:

The method of Claim 28 practiced with elements A, B, and C:

A. A particular treatment substance (Applicants required to select one)

- urease inhibitor,
- nitrification inhibitor,
- urease inhibitor and nitrification inhibitor,
- urease inhibitor and beneficial compound,
- nitrification inhibitor and beneficial compound, or
- urease inhibitor, nitrification inhibitor, and beneficial compound. Note: if a combination with beneficial compound is elected, then also indicate a particular beneficial compound;

B. A particular route of administration (Applicants required to select one)

- oral,
- bladder, or
- catheter; and

C. A particular vehicle for the treatment substance (Applicants required to select one)

- solution,
- delivery device where treatment substance is in core or impregnated in the device, or
- delivery device includes an electrochemical cell

Response to Election of Species Requirement

Applicants elect the following species:

- A. Treatment substance: a nitrification inhibitor. Claims 28, 30, 37, 40-42 and 44-67 read on this species.
- B. Route of administration: oral. Claims 28, 30, 37-55, 60-65 and 67 read on this species.

C. Vehicle for treatment substance: solution. Claims 28, 30, 37-52, 56, 59 and 66 read on this species. Applicants note that, with regard to Claim 51, the treatment substance may be incorporated into animal feed as a solution.

Claims 28, 30, 37, 40-42 and 44-52 read on all of the elected species. However, the foregoing elections are made with traverse, because, contrary to the assertions of the Examiner, the features recited in independent Claim 28 do relate to a special technical feature as defined in the PCT.

Traversal of Restriction Requirement

The Examiner has asserted that the features of Claim 28 would be obvious over Varel et al. in view of Ludden et al. (J. Anim. Sci. 2000 78:188-198). Varel et al. teach that application of a urease inhibitor to animal pens can control ammonia emissions from animal wastes in the pens. The Examiner combined this reference with Ludden et al., which the Examiner alleges discloses administration of a urease inhibitor via ruminant canula to livestock to reduce urease activity. However, the express purpose of the administration of the urease inhibitor in Ludden et al. was "as a means of retarding the rapid degradation of dietary urea in ruminant livestock." *See, e.g.* page 188, second column. As discussed on page 197, middle of first column, of Ludden et al., the urease inhibition strategy was designed to "improve animal performance." Thus, the purpose of administering urease inhibitor to the animals in Ludden et al. had nothing to do with the claimed "reducing loss of nitrogen from soil exposed to waste from animals." Thus, one having ordinary skill in the art would not look to Ludden et al. to identify a mechanism for achieving this result.

Moreover, because Ludden et al. were concerned only with improving animal performance, they did not measure any parameter from which the effect on reducing loss of nitrogen from soil exposed to waste from animals could be ascertained. Ludden et al. did measure certain effects on excretion of N compounds from animals treated with urease inhibitors. For example, on page 193, first column, Ludden et al. reported that *Experiment 1* resulted in an increase in fecal N excretion and in urinary urea and ammonia excretion, but no difference in urinary urea N excretion. Ludden et al. also reported the results of *Experiment 2* on page 193, second column. It was found that fecal N excretion was unaffected by urease inhibitor. Similarly, on page 196, first column, Ludden et al. reported that *Experiment 3* showed that N excretion increased with increasing urease inhibitor. Thus, the results of Ludden et al. were that

treatment of animals with urease inhibitor tended to either increase excretion of N-compounds or that such compounds stayed the same.

As described in Applicants' specification at page 1, lines 19-21, the "loss of nitrogen from soil exposed to waste from animals" addressed by the presently claimed invention can result from a number of mechanisms. These mechanisms include (a) conversion of nitrogen-containing compounds (e.g. urea) to atmospheric nitrogen (e.g. nitrous oxide), (b) volatilization of ammonium salts to ammonia, (c) runoff and (d) leaching in which nitrates move through the soil into groundwater. *See*, Applicants' specification at page 2, lines 1-6. Thus, the presence of any of a variety of nitrogen compounds, including urea, ammonium salts and nitrates, in the excretions of the animals can lead to the recited "loss of nitrogen from soil." Since the only data reported by Ludden et al. were either an increase or no change in nitrogen excreted by the animals, the only data reported by Ludden et al. would lead one skilled in the art to expect either an increase or no change in loss of nitrogen from soil. As such, the Ludden et al. reference actually teaches away from the presently claimed invention.

It is well established that a "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." M.P.E.P. 2141.02(VI). Thus, in light of the teaching of Ludden et al. away from the presently claimed invention, the cited combination of Varel et al. with Ludden et al. simply would not lead one having ordinary skill in the art to the presently claimed invention of Claim 28.

The Applicants have unexpectedly discovered that the presently claimed invention addresses the loss of nitrogen from soil by "slowing the rate of transformation of urea to nitrate, through the inhibition of ureases produced by bacteria in the soil, by slowing the nitrification of ammonium to nitrate, and enhancing the immobilization of inorganic nitrogen into soil organic forms." Applicants' specification at page 15, lines 1-4. These results are supported by the experimental data shown in Figures 1-9 and the accompanying text in Applicants' specification. Nothing in the cited prior art references would lead one having ordinary skill in the art to expect such results. These unexpected results further support the nonobviousness of Claim 28.

Because the limitations of Claim 28 are in fact patentable over the prior art, the features of this claim do constitute a special technical feature as defined in the Patent Cooperation Treaty. Accordingly, the requirement for election of species is improper and should be withdrawn.

Conclusion

Even if Applicants' traversal of the requirement is not successful, immediate examination of Claims 28, 30, 37, 40-42 and 44-52, is respectfully requested, and upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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